

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
OFFICE OF FINANCIAL AND INSURANCE REGULATION
Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXXX

Petitioner

v

File No. 123245-001

Midwest Health Plan, Inc.

Respondent

Issued and entered
This 12th day of September 2011
by R. Kevin Clinton
Commissioner

ORDER

I. BACKGROUND

XXXXXX (Petitioner) is enrolled for health care coverage with Midwest Health Plan, Inc. (Midwest), a Medicaid-only health maintenance organization. Her health care benefits are defined in a Certificate of Coverage (the certificate) issued by Midwest.

The Petitioner, X years old, has a history of usual interstitial pneumonia (UIP) and secondary pulmonary hypertension as well as coronary artery disease. Her pulmonary function had deteriorated to the point where she was evaluated for a possible lung transplant by both XXXXXX Hospital and the XXXXXX Hospital. Both facilities are part of Midwest's provider network and both declined to make her a candidate for a lung transplant.

On August 23, 2011, without authorization from Midwest, the Petitioner was transferred from the XXXXXX Hospital to the XXXXXX Clinic for further evaluation as a candidate for a lung transplant. The XXXXXX Clinic is not in Midwest's provider network.

On August 29, 2011, the XXXXXX Clinic asked Midwest to authorize coverage for a double lung transplant. Midwest completed an expedited internal review and issued a final adverse determination dated September 1, 2011, denying coverage for the transplant.

On September 6, 2011, Dr. XXXXXX, authorized representative of the Petitioner, asked

the Commissioner to conduct an expedited external review of Midwest's final adverse determination under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* In order to receive an expedited external review, a physician must substantiate that the review involves a medical condition of the covered person where failure to complete a quick review "would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function...." See MCL 550.1913(1)(a). Dr. XXXXX substantiated Petitioner's need for an expedited external review in her September 6, 2011, letter.

The Commissioner reviewed the request for an expedited external review and accepted it on September 7, 2011. The matter was assigned to an independent review organization for analysis and recommendation.

In addition to the request for authorization for the lung transplant, the Petitioner and the XXXXX Clinic also raised issues relating to coverage for the transportation of the Petitioner from the XXXXX to the XXXXX Clinic, her inpatient admission at the clinic, and her evaluation as a transplant candidate. However, the sole issue in this expedited external review is whether Midwest must authorize coverage for the lung transplant. The Commissioner can only review prospective adverse determinations in an expedited review. See MCL 550.1913(11). The other issues may be resolved in a separate review and order.

II. ANALYSIS

The Midwest certificate covers organ and tissue transplants. In "Appendix II – Services Covered by the Plan," it says:

7. Organ and Tissue Transplants are covered including the Hospital and professional medical services required to receive a non-experimental transplant of a human organ or body tissue as defined by, and according to, established utilization guidelines used by MHP. Transplants of artificial organs are not covered. Medicaid will pay for the Covered Services for donors if the donor does not have transplant benefits under any other health care plan. The total payment for all services combined for each specified organ transplant type is limited to a one million dollar (\$1,000,000) lifetime maximum.

In its September 1, 2011, final adverse determination, Midwest gave these reasons for denying authorization for the transplant:

- International and XXXXX Clinic Criteria for lung transplant require the member to demonstrate 6 months of smoking cessation as evidenced by negative urine screens. The member had a positive screen for nicotine in April 2011.

- Criteria for Transplant includes that member be able to tolerate the post operative course of treatment after transplant. Member has CHF [*congestive heart failure*] which would cause problems for the member to tolerate the post operative treatment course.
- Michigan Medicaid Provider Manual considers requests for exceptions from transplant criteria as Investigational/Experimental Trials. If the XXXXX Clinic requests an exception from their Transplant criteria, Midwest Health Plan would consider the Transplant as Investigational/Experimental and is prohibited by the Michigan Medicaid Provider Manual to reimburse for that care.

The Petitioner's authorized representative responded to Midwest's reasons for denying coverage in a September 2, 2011, letter:

2. International and XXXXX Clinic criteria for lung transplant require 6 months of smoking abstinence.

Response: These are general criteria, for which exceptions are made on a case by case basis and have an exception clause for critically ill patients. The patient quit smoking in April 2011 and the XXXXX Clinic Selection Committee comprised of a multidisciplinary team of clinicians is comfortable with accepting 4.5 months of abstinence along with a behavior contract. Furthermore the State of Ohio has a medical review board, the Ohio Solid Organ Consortium (OSOTC), comprised of physician and transplant related personnel who in a blinded review vote on candidates to be listed for lung transplantation. ...[T]he OSOTC approved XXXXX as an appropriate candidate.

3. Criteria for transplant include member tolerating post operative course / presence of CHF.

Response: Of lung transplants at XXXXX Clinic in 2010, 56 had the same diagnosis of UIP and over 50% of them presented with secondary pulmonary hypertension as evidenced by RHC (mPAP 40 mmHg). We do not agree that XXXXX has CHF as documented in the denial. XXXXX, with all of our lung transplant recipients, will have an outstanding opportunity to make a full recovery and tolerate a post operative course given the expertise of clinical staff and extensive experience with UIP pre transplant candidates. This is evidenced in the multiple referrals from XXXXX.

4. Michigan Medicaid considers requests for exceptions from transplant criteria as Investigational / Experimental.

Response: Lung transplantation is not experimental, it is an accepted treatment for

end stage lung disease and is recognized by ISHLT as such and demonstrated by the first line of international guidelines. Both the XXXXX Clinic Lung Transplant Team and the OSOTC felt that transplantation was the only suitable treatment for this patient and her end stage disease.

The question of whether Midwest had correctly categorized the requested surgery as experimental/investigational was submitted to an independent review organization (IRO) for analysis as required by Section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6). The IRO submitted its recommendation on September 8, 2011.

The review was conducted by a physician who is board certified in surgery and critical care surgery; specializes in transplant surgery; and has been in practice for more than 18 years. The reviewer is familiar with the medical management of patients with the Petitioner's condition. The IRO report had this analysis:

[T]he...member has been diagnosed with end stage lung disease....[T]he member was evaluated at the XXXXX Clinic and was determined to be an acceptable candidate for a double lung transplant at that center....[T]he member underwent a cardiac catheterization and was cleared for the transplant by cardiology.

[T]he...member's case was reviewed by the independent Ohio Solid Organ Transplant Committee and that the requested transplant was approved by this committee....[L]hat lung transplantation is the only treatment modality that will offer the member an opportunity for long-term survival....[L]ung transplantation is not experimental/investigational for treatment of the member's condition....[T]ransplant centers are granted the authority to make listing decisions by UNOS [*United Network for Organ Sharing*] using their established guidelines....[I]t is therefore appropriate to list the member for a double lung transplant as she has not only been approved by the multi-disciplinary team at the XXXXX Clinic but also approved by the State of Ohio's oversight committee.

Pursuant to the information set forth above and available documentation, the [reviewer] determined that the requested double lung transplant at the XXXXX Clinic is not experimental/investigational for treatment of the member's condition, that these services are medically necessary for treatment of the member's condition and that the rejection of coverage for these services was incorrect.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded deference by the Commissioner; in a decision to uphold or reverse an adverse determination the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b). The IRO reviewer's analysis is based on extensive expertise and professional judgment and the Commissioner can discern no reason to reject the

recommendation in this case.

The Commissioner accepts the IRO reviewer's determination that the Petitioner's requested double lung transplant is not experimental or investigational and is medically necessary for treatment of her condition.

III. ORDER

The Commissioner reverses part of Midwest's final adverse determination of September 1, 2011. Midwest shall cover the Petitioner's double lung transplant surgery at the XXXXX Clinic and shall, within seven days of providing coverage, provide the Commissioner proof it has implemented this order.

To enforce this order, the Petitioner may report any complaint regarding implementation to the Office of Financial and Insurance Regulation, Health Plans Division, toll free at (877) 999-6442.

Under MCL 550.1915, any person aggrieved by this order may seek judicial review no later than sixty days from the date of this order in the circuit court for the county where the covered person resides or the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.

R. Kevin Clinton
Commissioner